Purpose

The purpose of this Guide is to outline the steps to conduct internal audits and management reviews.

Scope

This Guide applies to all activities of the Ionizing Radiation Division that pertain to the calibration and testing services.

Definitions

N/A

Equipment

N/A

Health & Safety Precautions

N/A

Protocol

Internal audits

1. The Quality Manager will develop an audit schedule that will, over the course of one year, verify that the IRD operations continue to comply with the requirements of this quality system and the NIST Quality System.

2. Audits will be scheduled to correspond with the anticipated schedule of each activity.

3. The audit schedule will be provided to the Group Leaders at least one month prior to the proposed audit. The audits shall be conducted by the Quality Manager, Deputy Quality Manager, or the Group Leaders may designate someone within their Group to conduct each audit.

4. Unscheduled audits may be performed at any time at the discretion of the Quality Manager, Group Leader or Division Chief.

5. Based on the compliance requirements for an activity, the auditor should develop a checklist for the audit. This checklist should include:

    5.1 A list of objective requirements based on the quality system documentation and the scope of the audit.

5.2 A means of noting acceptability for each checklist item (i.e., pass/fail, yes/no/N/A, etc.)

5.3 A section for notes to document the basis for acceptability (or unacceptability) of a checklist item.

5.4 Pages numbered to ensure that each page is traceable to the rest of the checklist and notes.

5.5 The date of the audit and a place for the signature of the auditor on each page.

5.6 The audit number assigned by the Quality Manager.

6. The auditor will provide a copy of the checklist to the Quality Manager before starting the audit.

7. Using the checklist, the auditor evaluates compliance with requirements by observing activities in progress, interviewing personnel, reviewing documentation or records, and reviewing procedures.

8. The auditor brings any conditions identified as requiring corrective actions during the assessment to the attention of the Group Leader and the individual(s) involved.

9. Appropriate personnel must notify any clients in writing if investigations show that their laboratory results may have been affected.

10. Upon completion of the assessment, the auditor reviews the results with the Group Leader.

11. The auditor documents any findings (including those corrected during the audit) and initiates Corrective Action Plans (IRD-G-08) or Preventive Actions (IRD-G-09) as appropriate.

12. After completion of the audit, the auditor prepares a report to include the following:

12.1 The audit number.

12.2 The inclusive dates of the audit

12.3 The scope of the audit, including a concise description of the activity under surveillance, and the governing requirements document.

12.4 The auditors name.

12.5 Key persons contacted during the course of the audit.

12.6 A summary of the results of the audit, including any exemplary practices, and any findings noted including corrective or preventive actions taken.

13. The report is then signed by the auditor, dated, and given to the Quality Manager who files it with the checklist in the appropriate file cabinet.

Management reviews

Management reviews are set by the NIST-QM-I; see Section 4.6.2 of that document.

Follow-up audits and reviews

1. Follow-up actions on audit and review findings shall begin in a timely fashion.

2. If neither a corrective action plan nor preventive action form were initiated, findings will be answered to in writing by the individual involved. The answer will be provided to the auditor.

3. The auditor will check the response to ensure that the finding is addressed properly. A follow-up audit or review may be conducted if necessary.

4. Once the auditor is satisfied, the response is given to the Quality Manager to file with the checklist and report.

Acceptance Criteria

N/A

References

IRD Quality System Documentation

Documentation

Audit schedule
Audit or review checklist
Internal audit or management review report and attachments

Filing and Retention

The Quality Manager shall file all documents in a file cabinet by date of audit. The retention time for audit files will be five years.